

(iv) You must notify the Center for Veterinary Medicine at the above address within 30 days of any change in name or business address.

(2) If you are a distributor who ships an animal feed containing a VFD drug to another consignee-distributor in the absence of a valid VFD, you must obtain an "acknowledgment letter," as defined in § 558.3(b)(11), from the consignee-distributor. The letter must include a statement affirming that the consignee-distributor has complied with "distributor notification" requirements of paragraph (d)(1) of this section.

(e) What are the additional record-keeping requirements if I am a distributor?

(1) You must keep records of receipt and distribution of all medicated animal feed containing a VFD drug.

(2) You must keep these records for 2 years from date of receipt and distribution.

(3) You must make records available for inspection and copying by FDA.

(f) What cautionary statements are required for VFD drugs and animal feeds containing VFD drugs? All labeling and advertising must prominently and conspicuously display the following cautionary statement: "Caution: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice."

[65 FR 76929, Dec. 8, 2000, as amended at 72 FR 69131, Dec. 6, 2007]

§ 558.15 Antibiotic, nitrofurantoin, and sulfonamide drugs in the feed of animals.

(a) The Commissioner of Food and Drugs will propose to revoke currently approved subtherapeutic (increased rate of gain, disease prevention, etc.) uses in animal feed of antibiotic and sulfonamide drugs whether granted by approval of new animal drug applications, master files and/or antibiotic or food additive regulations, by no later than April 20, 1975, or the nitrofurantoin drugs by no later than September 5,

1975, unless data are submitted which resolve conclusively the issues concerning their safety to man and animals and their effectiveness under specific criteria established by the Food and Drug Administration based on the guidelines included in the report of the FDA task force on the use of antibiotics in animal feeds. All persons or firms previously marketing identical, related, or similar products except the nitrofurantoin drugs not the subject of an approved new animal drug application must submit a new animal drug application by July 19, 1973, or by December 4, 1973, in the case of nitrofurantoin drugs, if marketing is to continue during the interim. New animal drug entities with antibacterial activity not previously marketed, now pending approval or submitted for approval prior to, on, or following the effective date of this publication, shall satisfy such criteria prior to approval.

(b) Any person interested in developing data which will support retaining approval for such uses of such antibiotic, nitrofurantoin, and sulfonamide drugs pursuant to section 512(l) of the Federal Food, Drug, and Cosmetic Act shall submit to the Commissioner the following:

(1) By July 19, 1973, records and reports of completed, ongoing, or planned studies, including protocols, on the tetracyclines, streptomycin, dihydrostreptomycin, penicillin, and the sulfonamides; for all other antibiotics by October 17, 1973; and for the nitrofurantoin drugs by March 4, 1974. The Food and Drug Administration encourages sponsors to consult with the Center for Veterinary Medicine on protocol design and plans for future studies.

(2) By April 20, 1974, data from completed studies on the tetracyclines, streptomycin, dihydrostreptomycin, the sulfonamides, and penicillin assessing the effect of the subtherapeutic use of the drug in feed on the salmonella reservoir in the target animal as compared to that in nonmedicated controls. Failure to complete the salmonella studies for any of these drugs by that time will be grounds for proceeding to immediately withdraw approval.

(3) By April 20, 1975, data satisfying all other specified criteria for safety

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and effectiveness, including the effect on the salmonella reservoir for any antibiotic or sulfonamide drugs and by September 5, 1975, for the nitrofurans drugs, approved for subtherapeutic use in animal feeds. Drug efficacy data shall be submitted for any feed-use combination product containing such drug and any feed-use single ingredient antibiotic, nitrofurans, or sulfonamide not reviewed by the National Academy of Sciences—National Research Council, Drug Efficacy Study covering drugs marketed between 1938 and 1962.

(4) Progress reports on studies underway every January 1 and July 1 until completion.

(c) Failure on the part of any sponsor to comply with any of the provisions of paragraph (b) of this section for any of the antibacterial drugs included in paragraph (b)(1) of this section, or interim results indicating a health hazard, will be considered as grounds for immediately proceeding to withdraw approval of that drug for use in animal feeds under section 512(l) of the act in the case of failure to submit required records and reports and under section 512(e) where new information shows that such drug is not shown to be safe.

(d) Criteria based upon the guidelines laid down by the task force may be obtained from the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

(e) Reports as specified in this section shall be submitted to: Food and Drug Administration, Center for Veterinary Medicine, Office of New Animal

Drug Evaluation (HFV-100), 7500 Standish Pl., Rockville, MD 20855.

(f) Following the completion of the requirements of paragraphs (a) and (b) of this section and the studies provided for therein:

(1) Those antibiotic, nitrofurans, and sulfonamide drugs which fail to meet the prescribed criteria for subtherapeutic uses but which are found to be effective for the therapeutic purposes will be permitted in feed only for high-level, short-term therapeutic use and only by or on the order of a licensed veterinarian.

(2) Animal feeds containing antibacterial drugs permitted to remain in use for subtherapeutic purposes shall be labeled to include a statement of the quantity of such drugs.

(g) The submission of applications and data required by paragraphs (a) and (b) of this section is not required for the continued manufacture of any Type A medicated article which is produced solely from a Type A article that is in compliance with the requirements of this section: *Provided*, That the Type A medicated article contains no drug ingredient whose use in or on animal feed requires an approved application pursuant to section 512(m) of the act and/or where the Type A article is approved by regulation in this part.

(1) The following antibacterial Type A articles manufactured by the designated sponsors are eligible for interim marketing based on their compliance with the requirements of this section:

Drug sponsor	Type A article	Species	Use levels	Indications for use
Fermenta Animal Health Co.	Bacitracin methylene disalicylate.	Chicken turkeys, swine, and cattle.	Sec. 558.76	Sec. 558.76.

(2) [Reserved]

[51 FR 8811, Mar. 14, 1986; 51 FR 11014, Apr. 1, 1986, as amended at 51 FR 28547, Aug. 8, 1986; 53 FR 20843, June 7, 1988; 54 FR 37098, Sept. 7, 1989; 54 FR 51386, Dec. 15, 1989; 55 FR 8460, 8462, Mar. 8, 1990; 56 FR 41912, Aug. 23, 1991; 56 FR 64702, Dec. 12, 1991; 57 FR 6476, Feb. 25, 1992; 57 FR 8577, Mar. 11, 1992; 57 FR 14639, Apr. 22, 1992; 58 FR 17515, Apr. 5, 1993; 58 FR 30119, May 26, 1993; 61 FR 51589, Oct. 3, 1996; 64 FR 992, Jan. 7, 1999; 64 FR 37673, July 13, 1999; 71 FR 16221, Mar. 31, 2006; 75 FR 16002, Mar. 31, 2010]